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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

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1621

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DELIVERY MODE

12/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's remarks and arguments filed on 11 Sep 2009 is acknowledged.
2. In view of applicants amendments to the claims the previous 112 2nd paragraph has been withdrawn.
3. However, applicants' arguments for the 103(a) rejection are not found persuasive and as such, the previous rejection has been maintained for the reasons of record made on made on 13 April 2009.

Response to Arguments

4. Applicant's arguments filed on 11 Sep 2009 have been fully considered but they are not persuasive.

The examiner acknowledges applicants' argument that GB 947643 fails to suggest the present invention and it does not even imply washing of the crystals.

The examiner contends, however, that GB 947643 indeed suggests the applicants present invention. GB 947643 teaches a preparation and purification of reduced coenzyme Q₁₀ from the oxidized form of coenzyme Q₁₀ in ethanol and adding excess of sodium borohydride in aqueous medium and the resulted yellow orange compound is diluted with water and the compound is extracted with petroleum ether. The petroleum extracts are washed with water and then dried, which results in crystallized form of reduced coenzyme Q₁₀, the pure hydroquinone of coenzyme Q₁₀. This may be recrystallized from alcohol-petroleum ether mixture.

With regard to claim 21, GB 947643 teaches conversion of oxidized coenzyme Q10 into reduced coenzyme Q10 using glacial acetic acid as a solvent [see page 2, reaction scheme and lines 22-24].

The examiner acknowledges applicants' argument that the secondary references do not overcome the deficiencies of GB 947643 with respect to rendering unpatentable the present invention, specifically the secondary references do not teach washing crystals.

The examiner contends, however, that secondary references do teach washing the crystals in their processes. For example, **Kijima et al** (US 4,061,660) teach, in an analogous process, washing of crystals with diethyl ether [see Example 1]. **Kijima et al** (US 4,039,573) additionally discloses an analogous washing process where zinc is the catalyst [see Example 3]. **Morita et al** (US 4,163,864) also shows an analogous washing process, where methanol is used for washing [see Example 1].

The examiner acknowledges applicants' argument that the secondary references are silent about impurities derived from hyposulfurous acid, hyposulfurous acid salts, ascorbic acids, esters of ascorbic acids or salts of ascorbic acids and since they do not disclose washing crystals or oil, it is not at all apparent why the cited references would render obvious the present invention. The rejection relies upon impermissible "hindsight".

The examiner contends, however, that the purpose of secondary references is to show the washings of crystals in an analogous process. With regard to impurities, applicants' specification acknowledges the impurities present in the reduced coenzyme

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Q₁₀ such as oxidized coenzyme Q₁₀, reducing agents such as sodium borohydride, and known reducing agents such as zinc and vitamin C species [see page 1 of the specification].

The obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it is permissible for the Examiner to rely on disclosures, which fairly teach embodiments of Applicant's invention. The claims require a multitude of elements, such as washing crystals of CoA Q₁₀, and it is reasonable for one of ordinary skill in the art to consider these elements being used together.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to start with the GB 947643 teachings and combine the teachings of known solvents for the purification process, to achieve the instant claims with a reasonable expectation success. It is after all a simple washing to remove impurities using suitable solvents. The selection a solvent is depends on the solubility of the impurities. Applicants are invited to provide a showing which is commensurate in scope with the claimed invention that clearly demonstrate that the claimed purification step results in some unexpected property over the prior art. Absent any showing of unusual and/or unexpected results, the art obtains the same effect on the purification of reduced coenzyme Q₁₀. The expected result would be an improved purification of reduced coenzyme Q₁₀ for the chemical industry.

Modifying such parameters is prima facie obvious because an ordinary artisan would be motivated to optimize the purification process to make the process more economical, since it is within the scope to exchange the solvents through a routine experimentation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-21 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **Merck & Co., Inc** (GB 947,643) and applicants' acknowledged prior art in view of **Kijima et al** (US 4,061,660), **Kijima et al** (US 4,039,573) and **Morita et al** (US 4,163,864) for the reasons set forth in the office action 13 April 2009.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621

/Daniel M Sullivan/
Supervisory Patent Examiner, Art Unit 1621